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877135, 354 12/08/92 PATENTS

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| JAF 14   |              |
| EXAMINER |              |
| 10/19/95 |              |
| ART UNIT | PAPER NUMBER |
| 1202     | 20           |

DATE MAILED: 03/27/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 1/17/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

- ☒ Claims 3-5, 7, 10, 21 and 22 are pending in the application.  
Of the above, claims are withdrawn from consideration.
- ☒ Claims 1, 2, 6, 8, 9, 11-20 have been cancelled.
- ☐ Claims are allowed.
- ☒ Claims 3-5, 7, 10, 21 and 22 are rejected.
- ☐ Claims are objected to.
- ☐ Claims are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed has been ☐ approved; ☐ disapproved (see explanation).
- ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on .
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

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Claims 3-6, 7, 10, 21, and 22 are pending.

Claims 3-5, 7, 10, 21, and 22 remain rejected under 35 USC 102/103 over Belleau et al., EP '526 and US '407 *for the reasons of record and case law cited.*  
Applicant's arguments have been carefully considered.

Prior art teaches and claims the racemic mixtures of the instant enantiomer as well as the existence of the individual optical isomers and their isolation. The optical isomers are also included within the scope of Belleau's invention with their intended use as antivirals, i.e. in pharmaceutical compositions. In view of the naming of the compound corresponding to the racemic form embraced in instant claims and a manner of making it and the express disclosure of optical isomers and the contemplated use of such compounds in compositions for antiviral use, the disclosure of Belleau constitutes an anticipation. Given the complete disclosure of Belleau, a person skilled in the art would have been put in possession of the instantly claimed (-)-enantiomer.

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It is well known in the art that one of a pair of isomers is much more active than other, discovery of the activity of the individual isomer is obvious to one skilled in the art. It is well known that the activity may reside in only one of the isomers or be greater in one of them than the other. Thus, it would have been obvious to one skilled in the art at the time of the filing to consider the instant optical isomer for an evaluation of the utility disclosed in Belleau.

The Brenner cited by applicants in overcoming the 102 rejection does not have the same fact situation as herein. The Francis reference over which the appealed claims in Brenner were rejected did not expressly include the individual isomers of the caprolactam compound disclosed therein. With respect to Kaplan and Rohm and Haas cited by applicant, "genus-species patents". Instantly claimed (-)-enantiomer is not merely a species of the generic disclosure, it is expressly disclosed and claimed in Belleau.

Applicant's affidavit filed 3/15/94 has been considered. The evidence presenting toxicity data for the claimed isomer was not persuasive. In re Adamson 125 USPQ 233 is particularly in point. The decision rendered in May cited by applicant does not overcome the instant rejection since May claims to the levo isomer were allowed based on a significant property not possessed by either the dextro isomer or racemate. No such evidence is seen in the instant record. <sup>To</sup> ~~The~~ say because the (-)-enantiomer is less toxic than the (+)-enantiomer it is unobvious over the racemate of Belleau, is to disregard the basic underlying principles of stereochemistry and what is well known by those skilled in the art regarding the likelihood of expected difference in physiological activities between two enantiomers of a given racemic pair. In re Jones cited by applicant is not seen at all to be relevant. In Jones, the prior art did not provide one skilled in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound. The fact herein is different, the instantly claimed (-)-enantiomer was expressly disclosed and claimed in Belleau. Therefore, it is applicant's burden to show patentability of an isolated, active component previously

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found in an old racemic mixture.

No rejection has been made under 35 USC 101 in the record. The "how to use" rejection is under 35 USC 112, first paragraph, see previous office action. Applicants have kindly provided new utility guidelines. The guidelines is proposed internal guidelines and is solely on utility under 35 USC 101. References filed by applicant have been carefully reviewed. The Japan Times, teaches a combination of 3TC and AZT better than AZT alone. The article also teaches that there is no evidence yet that 3TC prolongs life, and 3TC itself is not much of a winner. Abstracts of 32nd ICAAC and Abstracts of IXth International Conference on AIDS teach studies/trials to assess safety and activity of 3TC. Biotechnology law report and BioWorld Today teach 3TC is effective in phase II hepatitis B virus trial. Biochem. Therapeu article teaches the combination of 3TC and AZT.

The present specification discloses instant compounds as useful for the treatment of a viral infection, in particular HIV. There is no evidence of record or available in the art teach "how to use" instant compound for the urged utility.

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A facsimile center has been established in Group 1200, room 3C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or 305-3592.

Any inquiry concerning this communication should be directed to Examiner Tsang at telephone number (703) 308-4715.

TSANG:jd  
March 23, 1995

  
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PRIMARY EXAMINER  
GROUP 1200